

## **REMARKS**

Favorable reconsideration of this application in light of the following elections remarks is respectfully requested.

No claims having been canceled or added, the Applicants respectfully submit that claims 1-28 remain pending in this application.

### **Species Election Requirement**

The Examiner is also requiring an election of species between the disclosed species of antibody for prosecution on the merits. Currently, claims 1-5 and 22-24 are deemed generic with respect to this election.

The Examiner is also requiring an election of species between disclosed species of particle forming proteins. Currently, claims 1, 8-13 and 18-21 are deemed generic with respect to this species election.

The Examiner is also requiring an election of species between disclosed species of encapsulated substances. Currently claim 1 is deemed generic with respect to this species election.

### **Applicants' Species Election**

With respect to the disclosed species of antibody, the Applicants elect, with traverse, the “anti-human EGF receptor,” for prosecution on the merits and submit that support for this election is found in, *e.g.*, Example C-4 of the original disclosure. The Applicants submit that claims 1-5 and 22-24 remain generic with respect to this election. The Applicants further note that although a specific anti-human EGF receptor utilized in the referenced Example, the clone 7G7B6, this antibody was identified and used for purposes of example only and should not be construed as unduly limiting the broader terminology utilized in the pending claims.

With respect to the disclosed species of particle forming proteins, the Applicants elect, with traverse, the “modified hepatitis B virus surface-antigen protein” as recited in claim 8. The Applicants submit that claims 1-13 and 18-21 are generic with respect to this species election.

With respect to the disclosed species of encapsulated substances, the Applicants elect, with traverse, the “thymidine kinase (KSV1tk) gene derived from simple herpes virus” as recited in claim 15. The Applicants submit that at least claims 1 and 14 are generic with respect to this species election.

### **Arguments in Support of Traverse**

The Applicants maintain that the talismanic recitation of “independent and distinct” is not sufficient to warrant a species election where the members of the group disclosed in the

specification possess at least one property in common for which they are utilized in the claimed composition. MPEP § 803.02. In this instance, each of the identified of species are grouped be a common ability, specifically the ability to form nanoparticles, comprise an antibody or comprise substance that will disrupt the function of the targeted cells respectively.

The Applicants also note that conventional restriction practice allows for examination of a “reasonable” number of independent or distinct inventions and/or species in a single application. In light of recent office actions, it appears that certain groups within the USPTO have taken it upon themselves to decide that the only reasonable number is “1,” thereby essentially eliminating traditional Markush practice. Unless and until the Applicants are provided with or directed to some statutory or regulatory support for this new definition of “reasonable number,” the Applicants submit that the application of such a definition is arbitrary and improper. Accordingly, absent identification of some appropriate basis for these new practices, the Applicants submit that the identified species should be regrouped in some logical fashion to provide groups of a “reasonable number” of species for examination in this application.

The Applicants also note that MPEP § 803 provides that where the search and examination of all the claims in an application can be made without “serious burden,” the examiner *must* examine the claims on the merits, even if they include claims to independent or distinct inventions. The Applicants note that the automated searching tools, in conjunction with the provision of the disclosed amino acid and nucleotide sequences in CRF tends to remove any

“serious burden” with regard to the searching and examination inventions involving sequence listings. Accordingly, the Applicants request that the Restriction and Election requirements imposed in the Action be reconsidered and withdrawn or materially modified in compliance with the provisions of the MPEP.

The Applicants further note that in the response filed April 23, 2007, the Applicants contended that “the 72 varieties of ‘modified hepatitis B virus surface-antigen protein’ known to those skilled in the art” and “the 71 varieties of ‘thymidine kinase (KSV1tk) gene’ known to those skilled in the art” would have been recognized by one skilled in the art as encompassed by the original disclosure and that this recognition within the art was sufficient to render each member of the group would be obvious in light of any other member of the same group. The Applicants contend that these statements are sufficient to satisfy the requirements as recited by the Examiner, Action at 2, and, accordingly, no further restriction or election is warranted with respect to either the “modified hepatitis B virus surface-antigen protein” or the “thymidine kinase (KSV1tk) gene.”

For all of the above stated reasons, reconsideration and withdrawal of the pending species election requirements and favorable action on the elected claims in the instant application are earnestly solicited by the Applicants.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKY & PIERCE, PLC

By 

Donald J. Daley (Reg. No. 34,313)  
P.O. Box 8910  
Reston, VA 20195  
(703) 668-8000

  
DJD/GPB